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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,055	10/22/2003	Craig D. Friedman	501438.20501	7247

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WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP  
250 PARK AVENUE  
10TH FLOOR  
NEW YORK, NY 10177

EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,055

Applicant(s)

FRIEDMAN ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 13-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 and 60-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 6/8/2006.

**MAINTAINED REJECTIONS**

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich et al. (USPN 5,962,620). Reich discloses hydrophilic and hydrophobic polyether polyurethanes (title and abstract). Reich also discloses that the polyurethanes may be used to form a shape structure or device including tubing, catheters, stents, and the like (column 4, lines 59-60 and column 15, lines 7-8). Reich also discloses that hydrophilic polymers may include drugs and enzymes, and may be coated over the polyurethanes (column 3, lines 38-43 and column 15, lines 10-12). Reich further discloses encapsulation of drugs in preferably, high viscosity hydrophilic polymers (column 27, line 60 – column 28, line 2). The disclosures of Reich anticipate the claims.

***Response to Arguments***

4. Applicant's arguments, see page 17, filed 6/8/2006, with respect to the rejection of claim 11 under 35 USC 112 have been fully considered and are persuasive. The rejection of claim 11 under 35 USC 112 has been withdrawn.
5. Applicant's arguments, see pages 18-19, filed 6/8/2006 have been fully considered but they are not persuasive. Applicant argues that:
  - a. Reich teaches solid or liquid substrates rather than the resilient or flexible reticulated substrates of applicant's invention, and
  - b. Reich does not teach a coating, preferably hydrophilic, that is applied over a resilient or flexible, at least partially hydrophobic, reticulated elastomeric support scaffold.
6. In response to applicant's arguments, Reich teaches, in one embodiment, a substrate that is coated with an amphiphilic polymer having more hydrophobic properties, a hydrophilic polymer coated over the amphiphilic polymer having more hydrophobic properties, and a hydrophobic polymer optionally coated over the hydrophilic polymer (column 3, lines 38-44). The examiner is giving the instant claims the broadest most reasonable interpretation and as such the examiner is interpreting applicant's "scaffold" to either be a) Reich's substrate alone or b) Reich's combined substrate and amphiphilic layer. So applicant's "coating" in interpretations of the examiner can be seen as either a) Reich's hydrophobic and hydrophilic coatings combined as one layer or b) Reich's hydrophilic coating alone. Reich teaches the particular "scaffold" material such as hydrophobic polyurethane as well as the particular

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properties, soft, swellable, flexible, and so on and even "interpenetrating networks" (columns 1-4, 9-10, 16 and 20-21). It should also be noted that applicants teach various solid implant configurations in the instant specification (paragraph 0098). Thus, the solid and liquid substrate teachings of Reich are pertinent to applicant's invention. It is for these reasons, that the examiner respectfully disagrees with applicant's position and find that the teachings of Reich do read on "a coating, preferably hydrophilic, that is applied over a resilient or flexible, at least partially hydrophobic reticulated elastomeric support scaffold". Thus, the rejections over Reich have been maintained.

#### **NEW REJECTIONS**

##### ***Duplicate Claims***

7. Applicant is advised that should claims 7, 8 and 61 be found allowable, claims 62, 70 and 77 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

##### ***Claim Objections***

8. Claims 77 and 78 are objected to because of the following informalities: the period at the end of the claims is missing. Appropriate correction is required.

##### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Independent claim 2 and its depending claims 3-12 and 60-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for hydrophilic coatings, does not reasonably provide enablement for all coatings including hydrophobic coatings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of "a coating".

11. Claims 3 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "at least one therapeutic agent contained within the coating", does not reasonably provide enablement for "at least one therapeutic agent is secured to and/or supported by the scaffold" outside of the coating. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of "at least one therapeutic agent is secured to and/or supported by the scaffold". For the same reasons, it is the position of the examiner that the generic concept of "more than one therapeutic agent is secured to and/or supported by the scaffold" is not supported by the instant specification.

12. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "at least one therapeutic agent is contained within

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microspheres in the coating", does not reasonably provide enablement for "at least one therapeutic agent contained within microspheres" outside of the coating. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. A careful review indicates that the instant specification is not sufficient to support the generic concept of "at least one therapeutic agent contained within microspheres".

13. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of "**more than one** therapeutic agent"; the subject matter is not properly described as filed. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 3 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation, "at least one therapeutic agent is secured to and/or supported by the scaffold", however claim 2 from

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which it depends includes the limitation, "wherein said coating contains one or more therapeutic agents". It is unclear whether the therapeutic agent(s) in claims 3 and 60 are secured to and/or supported by the scaffold in the coating or if said agent is a separate ingredient outside of the coating.

16. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites the limitation, "at least one therapeutic agent is contained within microspheres", however claim 2 from which it depends includes the limitation, "wherein said coating contains one or more therapeutic agents". It is unclear whether the therapeutic agent in claim 4 is in the microspheres in the coating or if said agent is a separate ingredient found in the microspheres outside of the coating.

17. Claim 64 recites the limitation "after recovery to a working size and configuration is similar to the original size and shape before compression". There is insufficient antecedent basis for this limitation in the claim.

18. Claim 78 recites the limitation "the is formed" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Conclusion***

19. All claims have been rejected; no claims are allowed.



***Correspondence***

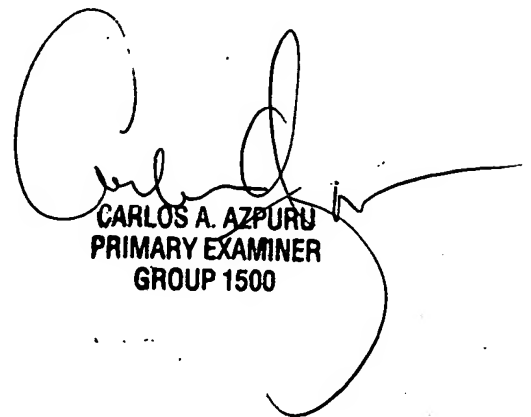
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian  
Examiner  
Art Unit 1615



CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500